Article 34

CLAIMS

What we claim is:

1. An immunogenic composition for *in vivo* administration to a host for the generation in the host of protective antibodies to respiratory syncytial virus (RSV) G protein, comprising a vector that will not replicate when introduced into the host to be protected comprising:

a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

a promoter sequence operatively coupled to said first nucleotide sequence for expression of said RSV G protein in the host, and

a second nucleotide sequence located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein *in vivo* from said vector in the host, and

a pharmaceutically-acceptable carrier therefor.

2. The composition of claim 1 wherein said first nucleotide sequence encodes a full-length RSV G protein.

3. The composition of claim 2 wherein said nucleotide sequence comprises the nucleotide sequence shown in Figure 2 (SEQ ID NO:1).

4. The composition of claim 2 wherein said first nucleotide sequence comprises the nucleotide sequence encoding a full length RSV G protein having the amino acid sequence shown in Figure 2 (SEQ ID NO:2).

5. The composition of claim 1 wherein said first nucleotide sequence encodes a RSV G protein from which the transmembrane coding sequence and sequences upstream thereto are absent.

6. The composition of claim 5 wherein said vector further comprises a heterologous signal peptide encoding nucleotide sequence immediately upstream of the 5'-terminus of said first nucleotide sequence.

7. The composition of claim 6 wherein said signal peptide encoding sequence encodes the signal peptide for human tissue plasminogen activator.

8. The composition of claim 5 wherein said first nucl otide sequence comprises the nucleotide sequence shown in Figure 3 (SEQ ID NO:3).

9. The composition of claim 5 wherein said first nucleotide sequence comprises a nucleotide sequence encoding a truncated RSV G protein having the amino acid sequence shown in Figure 3 (SEQ ID NO:4).

10. The composition of claim 1 wherein said promoter sequence is an immediate eady cytomegalovirus promoter.

11. The composition of claim 1 wherein said second nucleotide sequence is the human cytomegalovirus Intron A.

12. The composition of claim 1 wherein the vector is a plasmid vector.

13. The composition of claim 12 wherein the plasmid vector is pXL5 as shown in Figure 4.

14. The composition of claim 12 wherein the plasmid vector is pXL6 as shown in Figure 5.

15. A method of immunizing a host against disease caused by infection with respiratory syncytial virus (RSV), which comprises administering to said host an effective amount of a vector that will not replicate when introduced into the host to be protected comprising:

a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

a promoter sequence operatively coupled to said first nucleotide sequence for expression of said RSV G protein in the host, and

a second nucleotide sequence located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein *in vivo* from said vector in the host.

16. The method of claim 15 wherein said first nucleotide sequence encodes a full-length RSV G protein.

17. The method of claim 16 wherein said nucleotide sequence comprises the nucleotide sequ nce shown in Figure 2 (SEQ ID NO:1).

18. The method of claim 16 wherein said first nucleotide sequence comprises the nucleotid sequence encoding a full length RSV G protein shown in Figure 2 (SEQ ID NO:2).

19. The method of claim 15 wherein said first nucleotide sequence encodes a RSV G protein from which the transmembrane coding sequence and sequences upstream thereto are absent.

20. The method of claim 19 wherein said vector further comprises a heterologous signal peptide encoding nucleotide sequences immediately upstream of the 5'-terminus of said first nucleotide sequence.

21. The method of claim 20 wherein said signal peptide encoding sequence encodes the signal peptide for human tissue plasminogen activator.

22. The method of claim 19 wherein said first nucleotide sequence comprises the nucleotide sequence shown in Figure 3 (SEQ ID NO:3).

23. The method of claim 19 wherein said first nucleotide sequence comprises a nucleotide sequence encoding a transverse RSV G protein shown in Figure 3 (SEQ ID NO:4).

24. The method of claim 15 wherein said promoter sequence is an immediate early cytomegalovirus promoter.

25. The method of claim 15 wherein said second nucleotide sequence is the human cytomegalovirus intron A.

26. The method of claim 15 wherein the vector is a plasmid vector.

27. The method of claim 26 wherein said plasmid vector is pXL5 as shown in Figure 4.

28. The method of claim 26 wherein said vector is pXL6 as shown in Figure 5.

29. The method of claim 15 wherein a balanced Th1/Th2 immune response is induced.

30. A method of using a gene encoding a respiratory syncytial virus (RSV) G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein, to produce an immune response in a host, which comprises:

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isolating said gene,

operatively linking said gene to at least one control sequence to produce a vector that will not replicate when introduced into th host to be protected, said control sequence directing expression of said RSV G protein when introduced into a host to produce an immune response to said RSV G protein, and

introducing said vector into a host.

31. The method of claim 30 wherein said gene encoding a RSV G protein encodes a full length RSV G protein.

32. The method of claim 30 wherein said gene encoding a RSV G protein encodes a RSV G protein lacking the transmembrane domain and sequences upstream thereto.

33. The method of claim 32 wherein said vector further comprises a signal peptide encoding nucleotide sequences immediately upstream of the 5'-terminus of said first nucleotide sequence.

34. The method of claim 33 wherein said signal peptide encoding sequence encodes the signal peptide for human tissue plasminogen activator.

35. The method of claim 30 wherein said at least one control sequence comprises the immediate early cytomegalovirus promoter.

36. The method of claim 35 including the step of:

operatively linking said gene to an immunoprotection enhancing sequence to produce an enhanced immunoprotection to said RSV G protein in said host.

37. The method of claim 36 wherein said immunoprotection enhancing sequence is introduced into said vector between said control sequence and said gene.

38. The method of claim 37 wherein said immunoprotection enhancing sequence is the human cytomegalovirus Intron A.

39. The method of claim 30 wherein said gene is contained within a plasmid selected from the group consisting of pXL5 and pXL6.

40. A method of producing a vaccine for protection of a host against disease caused by infection with respiratory syncytial virus (RSV), which comprises:

isolating a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

operatively linking said first nucleotide sequence to at least one control sequence to produce a vector that will not replicate when introduced into the host to be protected, the control sequence directing expression of said RSV G protein when introduced to a host to produce an immune response to said RSV G protein,

operatively linking said first nucleotide sequence to a second nucleotide sequence to increase expression of said RSV G protein *in vivo* from the vector in the host, and

formulating said vector as a vaccine for *in vivo* administration to a host.

41. The method of claim 40 wherein said vector is selected from group consisting of pXL5 and pXL6.

42. A vaccine produced by the method of claim 40.

43. A method of determining the presence of a respiratory syncytial virus (RSV) G protein in a sample, comprising the steps of:

(a) immunizing a host with a vector tht will not replicate when introduced into the host to be protected to produce antibodies specific for the RSV G protein, said vector comprising:

a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

a promoter sequence operatively coupled to said first nucleotide sequence for expression of said RSV G protein in the host, and

a second nucleotide sequence located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein *in vivo* from said vector in th host,

(b) isolating the RSV G protein specific antibodies;

(c) contacting the sample with the isolated antibodi s to produce complexes comprising any RSV G protein present in a sample and said isolated RSV G protein-specific antibodies; and

(d) determining the production of the complexes.

44. The method of claim 43 wherein said vector is selected from the group consisting of pXL5 and pXL6.

45. A diagnostic kit for detecting the presence of a respiratory syncytial virus (RSV) G protein in a sample, comprising:

(a) a vector that will not replicate when introduced into the host to be protected capable of generating antibodies specific for the RSV G protein when administered to a host, the vector comprising:

a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

a promoter sequence operatively coupled to said first nucleotide sequence for expression of said RSV G protein in the host, and

a second nucleotide sequence located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein *in vivo* from said vector in the host;

(b) isolation means to isolate said RSV G protein-protein-specific antibodies;

(c) contacting means to contact the isolated RSV G specific antibodies with the sample to produce a complex comprising any RSV G protein in the sample and RSV G protein specific antibodies, and

(d) identifying to determine production of the complex.

46. The diagnostic kit of claim 45 wherein said vector is selected from the group consisting of pXL5 and pXL6.

47. A method for producing antibodies specific for a G protein of respiratory syncytial virus (RSV) comprising:

(a) immunizing a host with an effective amount of a vector that will not replicate when introduced into the host to be protected to produce RSV G-specific antibodies, said vector comprising:

a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

a promoter sequence operatively coupled to said first nucleotide sequence for expression of said RSV G protein in the host, and

a second nucleotide sequence located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein *in vivo* from said vector in the host; and

(b) isolating the RSV G-specific antibodies from the host.

48. A method of producing monoclonal antibodies specific for a G protein of respiratory syncytial virus (RSV) comprising the steps of:

(a) constructing a vector that will not replicate when introduced into the host to be protected comprising:

a first nucleotide sequence encoding a RSV G protein or a RSV G protein fragment that generates antibodies that specifically react with RSV G protein,

a promoter sequence operatively coupled to said first nucleotide sequence for expression of said RSV G protein in the host, and

a second nucleotide sequence located between said first nucleotide sequence and said promoter sequence to increase expression of said RSV G protein *in vivo* from said vector in the host;

(b) administering the vector to at least one mouse to produce at least one immunized mouse;

(c) removing B-lymphocytes from the at least one immunized mouse;

(d) fusing the B- lymphocytes from the at least one immunized mouse with myeloma cells, thereby producing hybridomas;

(e) cloning the hybridomas;

(f) selecting clones which produce anti-RSV G protein antibody;

(g) culturing the anti-RSV G protein antibody-producing clones; and then

(h) isolating anti-RSV G protein antibodies from the cultures.